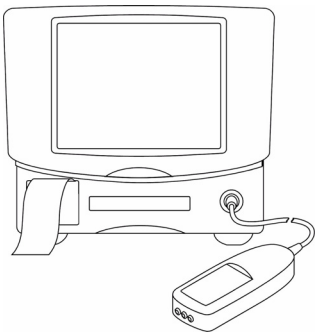
natus®



# Operator's Manual

## OLYMPIC CFM 6000

### Version 2

| | |
|---|---|
| ⚠ CAUTION | Read and be familiar with this manual before operating this device. To ensure operator, technician, and patient safety, use only as specified in this manual. |

CE 0086

602053A
DCN: 08-0175

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# Introduction

This manual provides the necessary information for installing, maintaining, and operating the Olympic CFM 6000 and the Olympic CFM cart. Olympic CFM 6000 is a cerebral function monitor (CFM) that monitors the state of the brain by acquiring an EEG signal and passing it through a special algorithm to display a continuous view of global electrocortical activity. It is suited for use in the NICU, ICU, PICU, emergency room, operating room, and clinical research laboratory.

The CFM 6000 should be used only under the direct supervision of a licensed medical practitioner who is trained in its operation and safe use.

## Indications for Use

The Olympic CFM 6000 is intended to be used by a variety of clinicians for the acquisition of electroencephalography (EEG) signals that can be used in conjunction with other clinical data to:

- Monitor the state of the brain.
- Determine and monitor long-term the neurological status of patients who may have suffered an hypoxic-ischemic event.
- Assist in the clinical management and treatment of a patient by monitoring neurological status to indicate how the treatment affects the neurological status.
- Assist in the prediction of neurological outcome.
- Monitor and record frequency and intensity of seizures to assist in the management of anticonvulsive therapy.
- Assist in the prediction of the severity of hypoxic-ischemic encephalopathy (HIE) and the long-term outcome in infants who have suffered an hypoxic-ischemic event.

# Warnings and Precautions

**WARNING**

**Electrical Grounding:**

- **Always connect the system power cord directly to a hospital-grade grounded power receptacle with a functional ground.**
- **To avoid electrical shock hazard, never touch the open rear-panel connectors and the patient at the same time. Always place connector covers over their receptacles when not in use.**

**Internal Voltage:**

- **To avoid electrical shock hazard, always turn off the CFM 6000 and unplug its power cord before cleaning the outer surfaces of the device or disassembling the device. For cleaning instructions, see *Cleaning and Maintenance* on page 28.**

**Liquids & Gases:**

- **Never use liquids on or near the CFM 6000. Fluid seepage into internal components creates a potential shock hazard. Never operate the system if internal components have been exposed to fluid.**

**Cables:**

- **Use of cables that exceed the lengths or are of different types than noted in the *Specifications* on page 36, may result in increased radio emissions or decreased RF immunity.**

**CAUTION**

**Operation:**

- Only properly trained medical and service personnel should operate and maintain the CFM 6000 and the CFM cart. As appropriate, maintain any records that indicate training attendance and completion.
- This device should only be used under the direct supervision of a licensed medical practitioner.
- Explosion hazard. Do not use in the presence of flammable anesthetics.

**Service:**

- Only technically qualified personnel should perform service procedures. On request, Natus Medical Incorporated will provide circuit diagrams, parts lists, and instructions to assist qualified technical personnel to repair the CFM 6000 to the printed circuit board (PCB) level. To obtain service, see *Service* on page 34.

**Detachable Components:**

- Never autoclave the CFM 6000 or its components as doing so will cause damage and void the warranty.

**Electromagnetic Interference:**

- Operation of this device may affect or be affected by other nearby equipment due to electromagnetic interference (EMI). If this occurs, place the devices further apart, re-orient the device cabling, or plug the devices into separate outlet circuit branches.
- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.
- Portable and mobile RF communications equipment can affect medical electrical equipment.

**CONT'D**

**CAUTION**

**USB Devices:**

- To meet electrical safety requirements, USB devices used with the CFM 6000 must meet the requirements of IEC 60601-1. Alternately, if line connected and approved to an appropriate national standard other than 60601-1, a separation device must be used (refer to IEC 60601-1-1).
- To avoid electrical shock hazard, ensure that the cover is securely placed over the USB port connector when not in use, and never touch the connector and patient simultaneously.

**Product Disposal:**

- The fluorescent lamp in the LCD display contains a small amount of Mercury. Follow your local ordinances and regulations for disposal.

# Conventions

The following conventions are used in this manual:

**Table 1** Conventions

| Convention | Description |
|---|---|
| **NOTE** | Provides additional information to clarify a point. |
| **NOTICE!** | Indicates situations that could result in damage to the equipment. |
| **CAUTION** | Indicates situations that, if not avoided, could result in minor to moderate injury to the patient or operator. |
| **WARNING** | Indicates situations that, if not avoided, could result in serious injury or death to the patient or operator. |

# Symbols

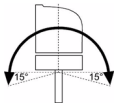
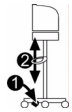
The following symbols are used on the CFM 6000, its accessories, or packaging.

**Table 2** Symbols

| Symbol | Definition |
|---|---|
| ~ | Alternating current (AC) |
| | Atmospheric pressure |
| | Attention, consult accompanying documents |
| EC REP | Authorized representative |
| | Defibrillation proof type-BF and complies with IEC Publication 601 |
| REF | Catalog number |

| Symbol | Definition |
|---|---|
| | Equipotential ground |
| LATEX | Latex free |
| LOT | Lot — the manufacturer's production identification number |
| | Manufacturer |
| | Mouse — this port is intended only for use in Service mode |
| | Network/Ethernet port |

**Table 2** Symbols, Continued

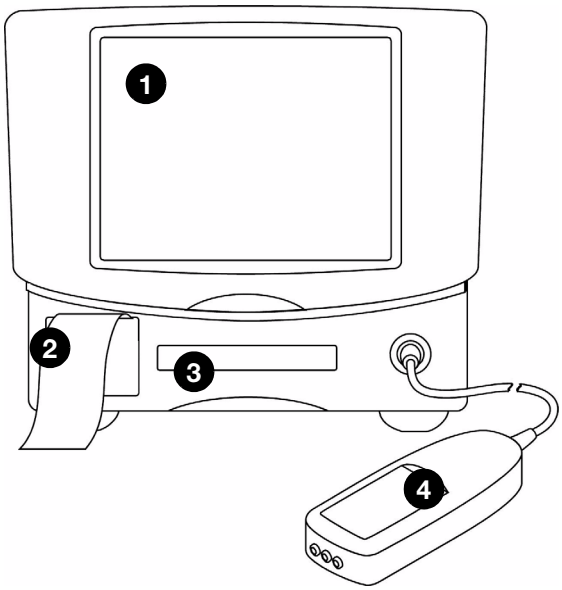
| Symbol | Definition |
|---|---|
|  | Cart tilt |
|  | Cart raise/lower |
| CE | CE mark |
| | Electrical shock hazard |
| 3 / Ag/AgCl | Package of three electrodes, Silver/Silver Chloride (Ag/AgCl) |
| 20 / | Bag of 20 electrode sets: 20 packages per bag |
| 5 / = 100 | Box of 100 electrode sets: five bags of electrodes per box |
| | Foot activated |
| | Fuse |
| | Ground |
| IOIOI | Input/output — RS-232 in/out serial port |
| | Keyboard — this port is intended only for use in Service mode |

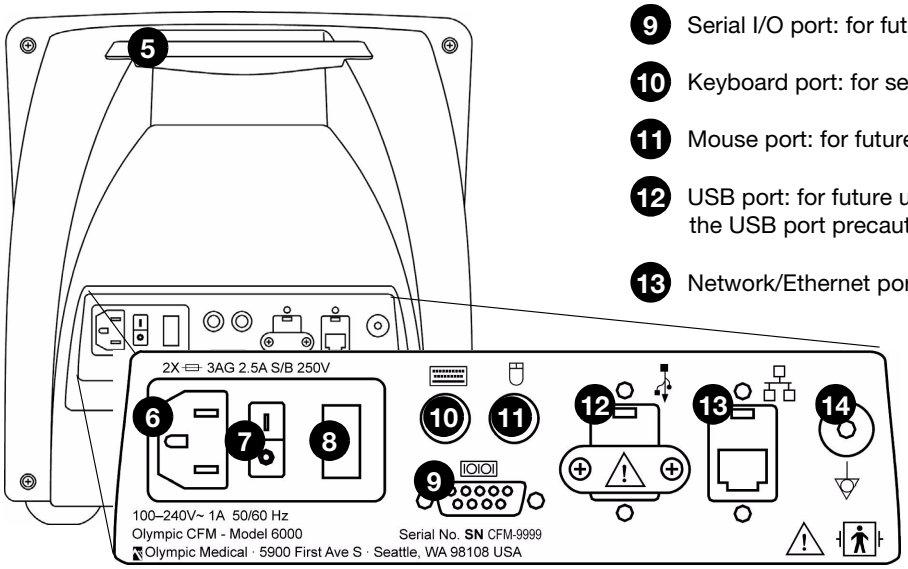
| Symbol | Definition |
|---|---|
| % | Percent humidity |
| I | Mains power ON |
| O | Mains power OFF |
| SN | Serial number |
| | Shipping specification |
| | Single use only — discard after use, do not sterilize |
| | Storage specification |
| | Temperature |
| | USB port — see the USB port precautions on page 3 |
| | Use by the expiration date |
| | Use indoors at normal room temperature and keep out of direct sunlight |

# CFM 6000 System

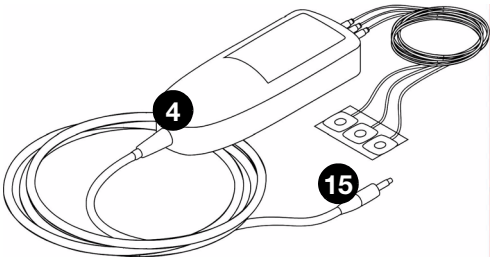
The CFM 6000 comes fully assembled with all the accessories (electrodes, NuPrep$_{TM}$ skin prep gel, printer paper, clips, and power cord) required to get started. Just plug in the power cord and the amplifier module, and the device is ready to operate.

## CFM 6000 Components




1. Touch screen: see *Understanding the CFM 6000 Screen* on page 13
2. Printer: see *Replacing Printer Paper* on page 25
3. CD-RW drive: for archiving patient files to compact disc and for updating software
4. Amplifier module: connects electrodes to the CFM 6000
5. Handle: use to carry the CFM 6000
6. Power cord receptacle: connects the CFM 6000 to a hospital-grade electrical outlet via power cord
7. Power on/off switch: use to turn the CFM 6000 power ON or OFF (see *Starting and Stopping the CFM 6000* on page 10)
8. Fuses
9. Serial I/O port: for future use
10. Keyboard port: for service use only
11. Mouse port: for future use only
12. USB port: for future use; shown with cover in place (see the USB port precautions on page 3)
13. Network/Ethernet port: for future use
14. Equipotential ground
15. Electrodes with touch-proof connectors: connect to the amplifier module (hydrogel electrodes shown)

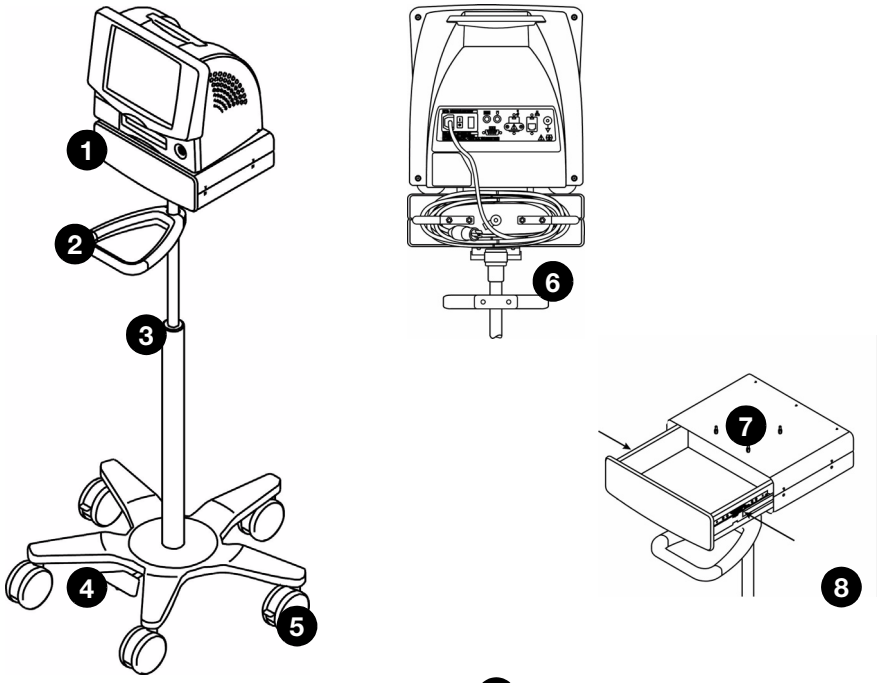


# CFM Cart

The optional Olympic CFM cart is intended for use with the Olympic CFM 6000. The cart makes it easy to use, move, and store the CFM 6000 and provides storage space for related accessories. For ordering information, see *CFM 6000 Catalog Items* on page 35.

For information about assembling the CFM cart, see *Assembling the CFM Cart* on page 30.

## CFM Cart Components




1. Storage drawer
2. Handle
3. Post
4. Foot pedal – for height adjustment
5. Footprint base with five caster wheels, two locking
6. Power cord clamp and cleats
7. Thumbscrews with spacers
8. Drawer slides

The storage drawer provides space for the following CFM 6000 accessories:

- Amplifier module
- Several packages of electrodes
- A tube of electrode cream or NuPrep™ Skin Prep Gel
- Several blank CD-R discs
- A roll of thermal imaging paper

# Using the CFM Cart

**CAUTION**

- Keep the CFM cart caster wheels locked during use to prevent the CFM 6000 from pulling on the electrode connections.
- Periodically inspect the caster wheels to ensure that the locking mechanism works correctly.

### To lock/unlock the two locking caster wheels:

- Press the wheel lock down to lock the wheel.
- Pull the wheel lock up to unlock the wheel.

**Figure 1** Locking/unlocking the caster wheels

### To adjust the height:

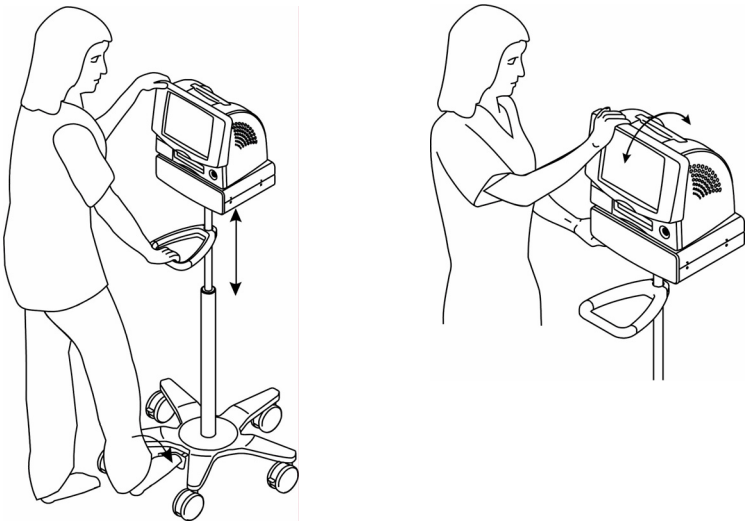
- Press the foot pedal while pulling the handle up to raise the device.
- Press the foot pedal while pushing the handle down to lower the device.

### To tilt the drawer assembly and the CFM 6000:

- With one hand on top of the CFM 6000 and the other on the bottom of the drawer, firmly tilt the drawer forward or backward.

  The drawer tilts up to 15º in either direction (up/down), allowing you to easily change the viewing angle and optimize touch-screen access from a seated or standing position.

**Figure 2** Adjusting the height and tilt



### To maneuver the CFM cart:

- Use the handle to move or maneuver the cart.

**To use the cart to transport the CFM 6000:**

1. Unplug the power cord of the CFM 6000 from the power receptacle, and wrap the excess cord around the cleats on the back of the drawer (see Figure 17 on page 33).
2. Ensure that the two locking wheels are in the unlocked position (see Figure 1).
3. Ensure that the CFM 6000 is not in a tilted position.
4. Ensure that the drawer is fully closed and latched.
5. Using the cart handle, push the cart forward.

# Olympic CFM 6000 Data Displays

The Olympic CFM 6000 records and displays three types of tracings: CFM, EEG, and impedance.

## CFM Tracings

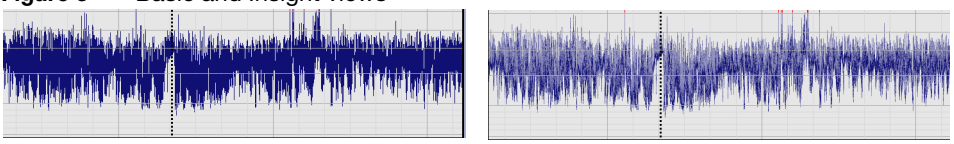
The CFM tracing indicates the overall electrocortical background activity of the brain by recording amplitude-integrated electroencephalography (aEEG). The EEG signal is filtered, rectified, and semi-logarithmically compressed. It is then displayed at a very slow chart speed, 1 mm per minute. A high reading on the chart indicates a high level of activity; a low value indicates low activity. The CFM 6000 screen shows three hours of a CFM tracing.

The CFM 6000 may be applied at any time, or used continuously, to determine the neurological status of a patient. A minimum of 20 minutes of trace should be observed to make a determination of neurological status. However, when there is a question about the presence of seizures, or potential changes in neurological status as a result of illness or other clinical treatment, it is generally best to observe the record for a longer, continuous period. The exact length of this period depends on the frequency of the seizures, or the condition or treatment being monitored. The CFM may record continuously for up to 30 days.

A CFM tracing is created by the continuous up and down movement of a digital pen responding to subtle variations in a brain's electrocortical activity. A tracing rises in response to increased activity and drops in response to lowered activity according to a fixed algorithm. With the pen moving at a very slow rate across the screen, 1 pixel width of CFM tracing reflects about 15 seconds of data.

Previous versions of the Olympic CFM 6000 offered only one view, CFM Basic. The CFM Basic view shows a series of vertical lines of different lengths, each of uniform density. This view shows no variation in the color of the 'ink.' CFM 6000 version 2.0 introduces a new and more sensitive view, CFM Insight. This view shows each vertical line with variable density that reflects the relative amount of time the brain spends at different levels of electrical activity, more closely approximating the trace generated by a CFM 5330 (Lectromed). Sometimes these two views are nearly identical; in other cases, Insight provides a clear gray-scale effect where a dark central band of activity can be seen, surrounded by lighter bands of activity above or below. This can be a valuable aid to identification of artifacts and can help identify certain conditions more clearly. The CFM 6000 now offers both views and the capability to toggle between them. The following illustration shows a tracing with both views.

**Figure 3** Basic and Insight views

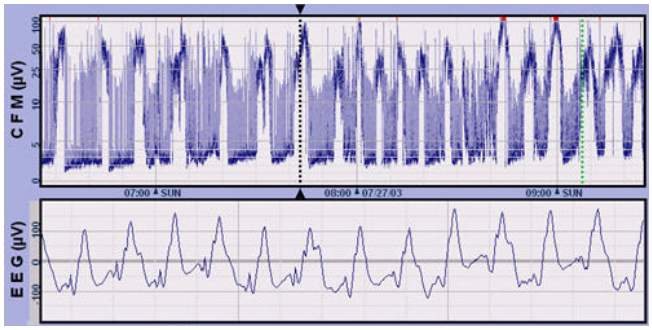


## EEG Tracings

The EEG tracing shows the underlying EEG detail that relates to the cursor position on the CFM tracing. The EEG cursor on the CFM tracing represents 15 seconds. The EEG window shows between 3 and 14 seconds of the EEG tracing at a time, depending on the EEG speed setting. The EEG can help confirm seizures and other brain activity. Display the EEG at a lower amplitude setting to see more detail; display it at a higher amplitude setting to show only major events. For information about changing speed and amplitude settings, see *Changing EEG Speed and Amplitude* on page 20.

The following illustration shows a CFM tracing with underlying EEG data.

**Figure 4** CFM tracing with EEG detail



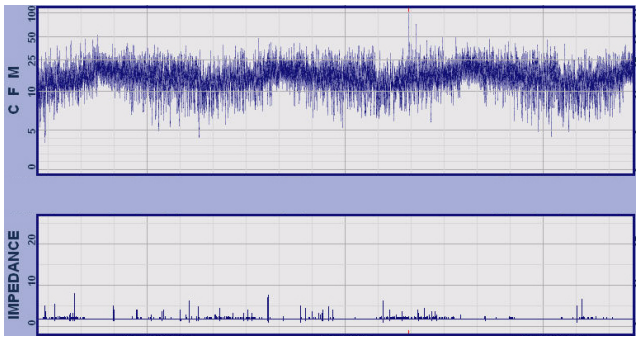

## Impedance Tracings

The impedance tracing indicates the connection quality (contact between the patient and the electrodes) and distinguishes noise. Impedance greater than 20 kΩ indicates that the electrodes should be reapplied or replaced. Occasional random spikes might occur when electrode conductivity changes for brief moments. The **Lead-Off** alert appears and sounds if the impedance becomes greater than 20 kΩ for more than three seconds.

**Tip**: To maintain good impedance when recording over long periods of time, it might be necessary to reattach or replace the electrodes periodically.

The following illustration shows a CFM tracing with the associated impedance tracing.

**Figure 5** CFM tracing with impedance



# Starting and Stopping the CFM 6000

### To start the CFM 6000:

1 Attach the power cord to the rear panel of the device, and then connect it to a hospital-grade electrical outlet. If the CFM 6000 is on a cart, lock the cart wheels.

2 Connect the amplifier module cord to the CFM 6000.

NOTE It is recommended that you connect the amplifier module to the CFM 6000 before placing electrodes on the patient.

3 Press the power switch to the **ON** (|) position, and wait for the CFM 6000 main screen to appear.

### To shut down the CFM 6000:

NOTE If recording is in process, first touch ✓**RECORD** to stop recording.

1 Press the CFM 6000 power switch to the **OFF** (O) position, and unplug the power cord from the electrical outlet.

2 Remove the electrodes from the patient and discard the electrodes.

CAUTION To avoid electrical shock hazard, ensure that the cover is placed over the USB port connector when not in use, and never touch the connector and patient simultaneously. For additional USB cautions, see page 3.

3 Unplug the amplifier module, and clean the device and module according to the instructions in *Cleaning and Maintenance* on page 28.

# Preparing the Patient — Applying Electrodes

NOTE
- Read the warnings and cautions on page 2 before operating this device.
- To obtain assistance or reorder items, see *Service* on page 34 and *Replacement Parts* on page 34.

### Required items:

- Electrodes — hydrogel or low-impedance needle
- Skin prep gel, such as NuPrep™ brand (if using hydrogel electrodes) (part no. 62060)
- 2x2 or 4x4 gauze pads (if using NuPrep skip prep gel)

- Adhesive tape, Coban™ wrap, or Kling® wrap (if using low-impedance needle electrodes)

**CAUTION**

- Medications may affect the patient's record. Anticonvulsants or sedatives may transiently suppress the CFM record. Administration of drugs or other clinical events should be noted to facilitate interpretation of the record.
- Poor electrode contact may cause high impedance. To ensure good electrode contact, always prepare the patient's skin before attaching the electrodes.

**NOTICE!**

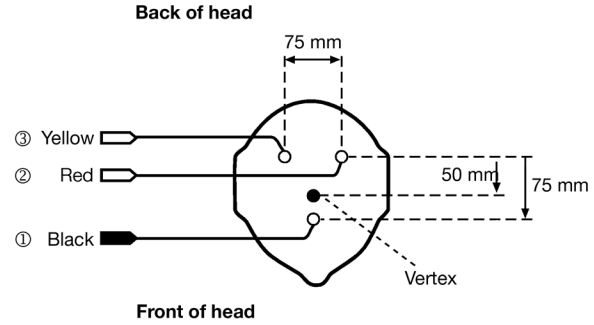
- For instructions and warnings relating to cleaning agents and skin prep gel (for example, alcohol wipes or NuPrep), consult the product instructions.

1. Verify that the amplifier module is connected to the CFM 6000 and that the CFM 6000 is turned on.
2. Determine whether to place electrodes biparietally or frontally and whether to use hydrogel or low-impedance electrodes, and then locate the areas of contact on the patient's head according to one of the following placement methods:

**NOTE** Depending on the type of electrodes used, color coding indicated below may not be applicable. The BLACK electrode is the ground; the YELLOW electrode is placed on the patient's right (left when facing the patient); and the RED electrode is placed on the patient's left (right when facing the patient).

**Placement method 1 — Biparietal placement for hydrogel or low-impedance needle electrodes:**

**Figure 6** Biparietal placement



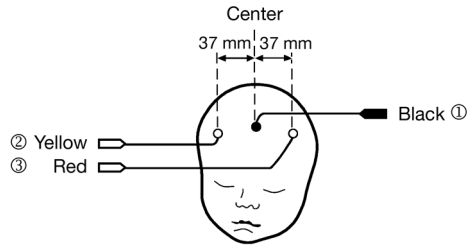

a. Locate the vertex and identify a point 25 mm anterior to it. The BLACK electrode (①) is to be placed at this location.

b. Locate a point approximately 50 mm posterior to the vertex. The RED electrode (②) is to be placed approximately 37 mm to the patient's left of this point (right if facing the patient).

c. The YELLOW electrode (③) is to be placed approximately 75 mm to the patient's right of the red electrode (left if facing the patient).

**Placement method 2 — Frontal placement for hydrogel electrodes (use this method if hair interferes with biparietal placement of hydrogel electrodes):**

**Figure 7** Frontal placement




a The BLACK electrode (①) is to be placed at the center of the patient's forehead as close to the hairline as possible.

b The YELLOW electrode (②) is to be placed approximately 37 mm to the patient's right of the center electrode (left if facing the patient).

c The RED electrode (③) is to be placed approximately 37 mm to the patient's left of the center electrode (right if facing the patient).

**3** Visually examine the electrode package for damage before opening it. Remove the electrode set from the package, and examine the electrodes and leads. If damage is apparent, discard the set.

**4** Clean and dry the areas of the patient's head where the electrodes are to be placed. Do not use alcohol for cleaning: alcohol can increase impedance.

**NOTE** It is recommended that you prep and place one electrode at a time when possible.

**NOTE** Where hair might present a barrier to good electrode contact, either shave the area or tamp down the hair with water during cleaning, and then pat dry.

**5** If using hydrogel electrodes, prepare the areas of contact prior to placement, as follows:

a Apply a small dot of skin prep gel, such as NuPrep, to each area of contact. You can use a 2x2 or 4x4 gauze pad to apply the NuPrep.

**NOTE** Always apply the skin prep gel directly to the skin. Never apply it directly to an electrode because it can increase impedance.

b Vigorously rub the NuPrep over the skin for 20 to 30 seconds, removing the surface layer of dead skin to improve conductivity. Ensure that the entire surface area to be covered by the electrode is prepared.

c Thoroughly remove the NuPrep with a new, clean gauze pad, and make sure the area is completely dry.

**6** After the area is prepared, attach the electrodes, as follows:

- For low-impedance electrodes, insert the needle subcutaneously up to the plastic hub and secure as you would an IV.
- For hydrogel electrodes, run a finger around the edges of the electrode for 20 to 30 seconds to ensure a secure seal.

7 Form a strain relief to minimize motion artifact by collecting the three leads into a bundle and tying the bundle into a small, loose loop near the electrodes. The strain relief loop should be as close to the electrodes as possible, while remaining isolated from them. Secure the loop to the patient's head with Coban™ or Kling® wrap. If desired, create a second strain relief loop near the amplifier end of the leads.

8 Connect the leads to the amplifier module, matching them to the corresponding color-coded receptacles, and clip the amplifier module to the patient's bedding.

# Operating the CFM 6000

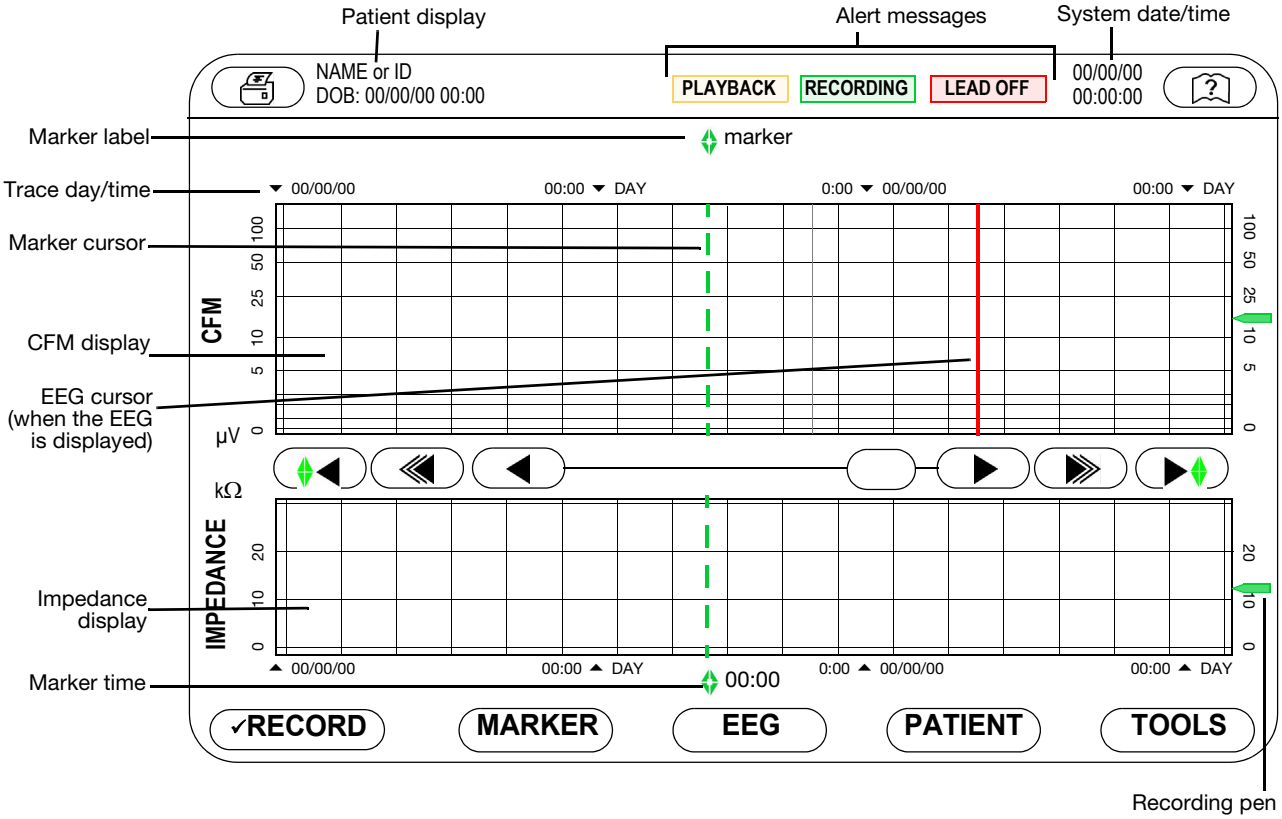
NOTE

- Read the warnings and cautions on page 2 before operating this device.
- To obtain assistance or reorder items, see *Service* on page 34 and *Replacement Parts* on page 34.

## Understanding the CFM 6000 Screen

The following illustration shows the location of major types of information on the CFM 6000 screen.

**Figure 8** Main screen



## Buttons

The following table describes the functions of buttons on the CFM 6000 screen. For information about buttons used to navigate EEG tracings, see *Viewing an EEG Tracing* on page 18.

| Button | Function |
|---|---|
| | Print. Touch to print the displayed tracing. |
| | Help. Touch to open Help. |
| | Previous/next marker. Touch to move the display to the previous or next off-screen marker. Touch and hold to jump to the beginning or end of the tracing.<br>If you scroll during recording and want to return to real-time display, touch and hold the next marker button. |
| | Auto-scroll. Touch to automatically scroll backward or forward through the tracing. Touch again to stop scrolling. When recording, the display returns from playback to real-time when the end of the trace is reached. |
| | Scrollbar. Touch or drag the bar or touch the buttons to scroll backward or forward through the tracing. Touch and hold to scroll quickly. When recording, the display returns from playback to real-time when the end of the trace is reached.<br>If you scroll during recording and want to return to real-time display, touch and hold the forward button until the end of the trace is reached or drag the scrollbar all the way to the right. |
| | EEG cursor or marker position. Touch to scroll the EEG cursor or a marker cursor backward or forward in 15-second increments. |
| | Close. Touch to close the active window. |
| | More. Touch to expand the active window, showing additional functions if available. |
| | Less. Touch to reduce the active window. Some functions might no longer show. |

## Alerts

Alerts are status messages that appear in color-coded boxes at the top of the CFM 6000 screen: green for normal, yellow for caution, red for stop and take action. For red alerts, a dialog box describes the action that is needed. For these alerts, take the appropriate action and press OK to close the dialog box, stop the alarm, and resume recording.

The possible alerts are the following:

| Alert | Meaning |
|---|---|
| **CALIBRATING** | **The system is performing a calibration check.** A calibration check occurs each time recording is started. It is important to wait for calibration to complete before attempting any other tasks. |
| **CALIBRATION** | **The calibration check failed.** The amplifier module needs to be replaced. |
| **CHECK SUM** | **The amplifier non-volatile RAM is corrupted.** The amplifier module needs to be replaced. |
| **COMM ERROR** | **A communication error occurred between the amplifier module and the CFM 6000.** Disconnect and reconnect the amplifier module. Replace the module if the problem is not corrected. |

| Alert | Meaning |
|---|---|
| **CONNECTION** | **The connection to the CFM 6000 is lost.** The amplifier module might have come loose. Check the connections to the amplifier and to the patient. |
| **LEAD OFF** | **An electrode is disconnected, or there is poor contact between the electrode and the patient.** Press **SILENCE** to silence the alarm for three minutes; press **DISABLE** to disable alarms for the remainder of the session. |
| **LOADING *xx*%** | **A session is loading from the hard disk.** |
| **MAX SIZE** | **The maximum size of the recording session has been reached.** The maximum recording session is 30 days. |
| **OVERLOAD** | (Appears as a red line at the top of the CFM tracing.) **The input level to the system is too high, and the CFM trace is locked above 100 µvolts.** |
| **PLAYBACK** | (Appears only during recording.) **The data displayed on the screen is not real time.** This alert appears when you scroll through the tracing or when you view a static EEG tracing. |
| **POWER INTERRUPT** | **Power was interrupted or the system reset.** Press **YES** to reload the file/session. Press **NO** to return to the start screen. |
| **RECORDING** | **CFM recording is in progress.** |

# Customizing Settings

Before beginning to record a patient session, customize the settings that are appropriate to your facility. You can customize the following:

- Predefined (standard) markers
- CFM tracing display style
- System date/time
- Language
- Operation mode (only for Natus Medical Incorporated service personnel)
- Capitalization used for data entry
- Types of patient information to be displayed while recording or viewing a patient session

## Changing Predefined (Standard) Markers

Markers are used to indicate the occurrence of significant events on CFM traces. You can customize the standard markers that come with the CFM 6000 to meet the needs of your facility. Changing a standard marker does not change any markers that were previously applied to CFM tracings.

### To change standard markers:

1. Touch **TOOLS**, and then touch **SETTINGS**.
2. Touch **MARKERS**, and then touch a marker label and use the displayed keyboard buttons to edit it.
3. Touch **ACCEPT** to save the change, and close the **TOOLS** window.

**Tip:** To confirm your changes and verify that all the predefined markers are correct for your facility, touch **MARKERS** and confirm the marker labels in the Standard Markers window.

## Changing the CFM Tracing Display Style

Tracings can be displayed according to preference. You can choose between CFM Insight (gray-scale) or CFM Basic (solid) and between light on a dark background or dark on a light background.

### To change the tracing display style:

1. Touch **TOOLS**, and then touch **SETTINGS**.
2. Touch **DISPLAY**, and choose between **DARK TRACING** and **LIGHT TRACING** and between **INSIGHT** (gray-scale) and **BASIC** (solid).
3. When finished, close the **TOOLS** window.

## Adjusting the System Date/Time

1. Touch **TOOLS**, and then touch **SETTINGS**.
2. Touch **DATE/TIME**, and select the format for the date.
3. Touch **TIME ZONE** to set the time zone relative to Greenwich Mean Time, and then touch **ACCEPT**.
4. Touch **DAYLIGHT SAVINGS TIME** to activate or deactivate Daylight Savings Time.
5. Touch **DATE** and use the provided calendar controls to set the system date, and then touch **ACCEPT**.
6. Touch **TIME** and use the provided clock controls to set the system time, and then touch **ACCEPT**.
7. When finished, close the **TOOLS** window.

## Language

To see CFM 6000 controls in a language other than English, customize the language setting.

### To change the default language:

1. Touch **TOOLS**, and then touch **SETTINGS**.
2. Touch **LANGUAGE**, and select the desired language.

**NOTE** After you install or update the system software, you need to reselect your preferred language.

3. When finished, close the **TOOLS** window.

## Changing the Operation Mode

Service mode is reserved for use by Natus Medical Incorporated representatives. A password is required to change the mode.

## Changing Data Entry Capitalization

On-screen controls are provided for entering data such as patient information and marker labels. You can choose how you want this data to be capitalized by setting the data entry options.

### To set data entry options:

1. Touch **TOOLS**, and then touch **SETTINGS**.
2. Touch **OPTIONS**, and select the type of capitalization to use.
3. When finished, close the **TOOLS** window.

## Changing Patient Information to Display

You can select the types of patient information to display on the CFM 6000 main screen during session recording or viewing. Use this feature to suppress the display of all patient information if you wish to protect the confidentiality of the patient.

### To select patient information to display:

1. Touch **TOOLS**, and then touch **SETTINGS**.
2. Touch **OPTIONS**, and then enlarge the window:
3. Select up to two types of patient information (such as patient name and date of birth) to display on the main screen, or touch to clear all fields to protect patient confidentiality.
4. When finished, close the **TOOLS** window.

# Recording a Session

As you record a patient's brain activity, the data is stored on the internal hard disk and the tracing is displayed on the screen. The default name for the file on the hard disk is *cfm* followed by the system date and time, in the format: cfm_mm_dd_yy_hh_mm. You can enter a patient name to make the file easier to locate for future viewing or archiving to CD. See *Entering Patient Information* on page 20 for instructions on entering patient information.

The **RECORD** button acts as a toggle to start and pause recording. Keeping the electrodes in place, you can pause and resume recording as often as desired, up to the maximum recording session of 30 days.

**NOTE**

The CFM 6000 hard drive can store approximately 20,000 hours of data. If you try to save a file when the hard drive is full, an error occurs. For information about checking available disk space or removing files to free up space, see *Managing Files* on page 26.

### To monitor and record a patient's brain activity:

1. Verify that the amplifier module is connected to the CFM 6000, the CFM 6000 is turned on, and the electrode leads are connected to the amplifier module. The electrodes should be attached to the patient as described in *Preparing the Patient — Applying Electrodes* on page 10.
2. Touch **RECORD**. If a patient session is already displayed on the screen, you are prompted to resume the session or start a new one. Touch **RESUME** to continue the current session or **NEW** to start a new session.

Alternatively, you can enter patient information and then start recording from the Patient window. Touch **PATIENT**, touch **NEW**, and then touch **YES** to create a new session. Enter patient information as described in *Entering Patient Information* on page 20, and then touch **YES** to start recording. If a different patient session is active, touch **END** to terminate that session so that you can enter new patient information.

3 Wait for the yellow **CALIBRATING** alert at the top of the screen to change to a green **RECORDING** alert before proceeding.

**CAUTION** Allow the calibration check to complete before touching controls to perform tasks.

During recording, you can do the following:

- Pause and then resume recording. If you resume a session, a restart marker is placed after a 10-minute gap on the CFM tracing.
- Enter patient data. (See *Entering Patient Information* on page 20.)
- Print the tracing displayed on the screen. (See *Printing a Tracing* on page 23.)
- Scroll through the tracing to review it. If you scroll during recording, the display changes to playback mode. To return to the real-time display, scroll forward to the end of the tracing. (See *Understanding the CFM 6000 Screen* on page 13.)
- Place markers on areas of interest. (See *Using Markers* on page 21.)
- Suppress the display of patient information on the main screen to protect patient confidentiality. (See *Changing Patient Information to Display* on page 17.)

### To stop or pause recording:

- Touch ✓**RECORD**.

### To resume recording:

1 Touch **RECORD**.

2 In the Resume Recording window, touch **RESUME**.

### To end a patient session:

1 Touch ✓**RECORD**.

2 Touch **PATIENT**, and then touch **END**.

**NOTE** It is recommended that you archive (backup to CD) each session when recording is complete. See *Archiving a Session to CD* on page 26 for more information.

## Viewing an EEG Tracing

You can display the underlying EEG data that is associated with a CFM tracing. The EEG can help confirm seizures and other brain activity or help identify artifacts.

During recording, you can monitor the live EEG, or you can view EEG data recorded earlier in the session. You can change the EEG speed and amplitude to see more or less detail.

### To view the EEG tracing:

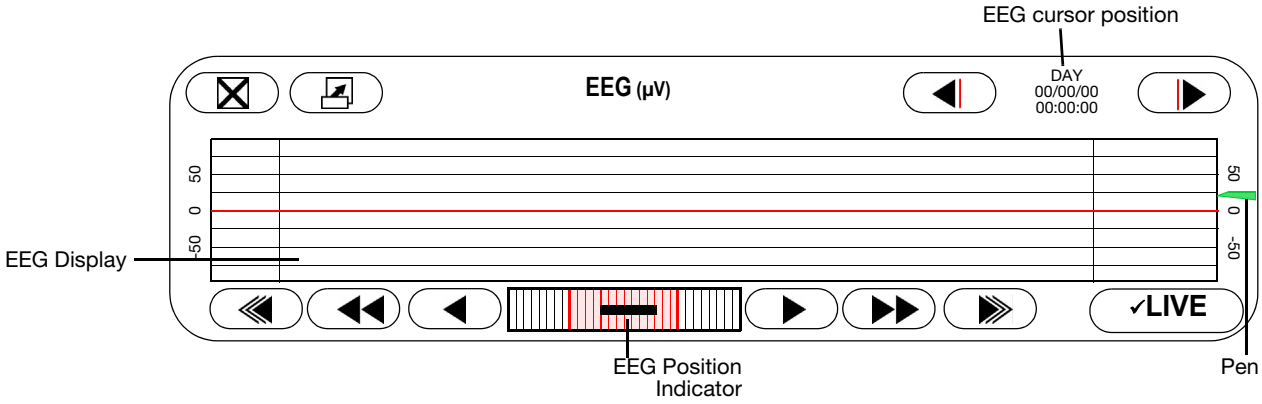
- With the patient's CFM tracing displayed, touch **EEG**. When you open the EEG view while recording when there is more the three hours of CFM data, the CFM 6000 switches to playback mode, so the displayed EEG data is not real-time.
- To monitor live EEG data while recording, touch **LIVE** to return to real-time display.

## Navigating an EEG Tracing

To locate an area in the EEG tracing to view, you can touch the CFM tracing at the desired location or use the navigation controls in the EEG window.

Figure 9 shows the EEG window. This window shows between 3 and 14 seconds of EEG tracing, depending on the EEG speed setting. By default, it shows six seconds at 30 mm/second. See *Changing EEG Speed and Amplitude* on page 20 for instructions on changing the speed setting.

**Figure 9** EEG window

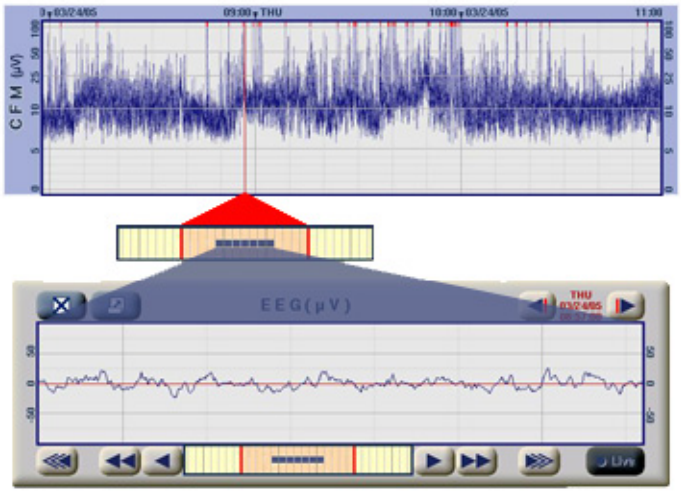



The following table describes the buttons and controls you can use to navigate the EEG tracing.

| Button | Function |
|---|---|
| ◀\| \|▶ | EEG cursor position. Touch to scroll the EEG cursor backward or forward in the CFM tracing in 15-second increments. |
| ⏪ ⏩ | Auto-scroll. Touch to automatically scroll backward or forward through the EEG tracing. Touch again to stop scrolling. |
| ◀◀ ▶▶ | Scroll about 2 seconds. Touch to scroll the EEG tracing backward or forward in approximately 2-second increments. Touch and hold to scroll quickly |
| ◀ ▶ | Scroll about 1/4 second. Touch to scroll the EEG tracing backward or forward in approximately 1/4-second increments. Touch and hold to scroll quickly. |

When the EEG tracing is displayed, a red cursor marks the associated area in the CFM tracing. This cursor represent 15 seconds of activity. The position of the EEG tracing within the cursor is represented on the EEG position indicator, as illustrated below:

**Figure 10** EEG Position Indicator




The EEG position indicator shows the following:

- The pink area in the position indicator represents the 15 seconds marked by the cursor in the CFM tracing.
- The dark horizontal bar in the position indicator illustrates where the displayed EEG tracing occurs within the cursor in the CFM tracing.
- The length and width of the dark horizontal bar changes as EEG speed and amplitude are changed. See *Changing EEG Speed and Amplitude* on page 20 for instructions on changing the speed and amplitude.

## Changing EEG Speed and Amplitude

Modify the speed and amplitude to increase or decrease the level of detail displayed in the EEG tracing.

### To change the EEG speed or amplitude:

1. With the EEG tracing displayed, touch to enlarge the EEG window and display the available options.
2. Select the desired speed in mm/sec. Increasing the speed decreases the amount of EEG tracing displayed in the window; decreasing the speed increases the amount of tracing displayed in the window.
3. Select the desired amplitude in µVolts. Amplitude indicates the upper and lower boundaries of the tracing. Decreasing the amplitude setting shows more detail; increasing the amplitude setting shows more major events.
4. Touch to reduce the EEG window and view the EEG tracing with the modified settings.

# Entering Patient Information

Patient information identifies a recording session, and includes patient name, patient ID, date of birth, and time of birth. You can enter patient information before, during, or after

recording. The patient name is used as the file name on the hard disk; if no patient name is entered, a default file name is used. (See *Recording a Session* on page 17.)

NOTE Once you enter patient ID, it cannot be changed.

If you do not want patient information to be displayed on the main screen while recording or viewing a patient session, see *Changing Patient Information to Display* on page 17.

### To enter patient information:

1 Touch **PATIENT**.

2 In the Patient window, touch a field to enter edit mode and use the provided controls to enter data for each field desired.

3 Touch **ACCEPT**.

You can use the Patient feature to create a new session, end a session, or open a stored session, as follows:

| Use this | To do this: |
|---|---|
| **END** | To end the active session so that you can start a new session or open another session. |
| **NEW** | To create a new patient session. |
| **OPEN** | To open a stored session. When you select the session you want from the list, the Information window opens briefly and then closes while the session opens. If the session is long, it might take several minutes to open. To avoid opening multiple files in sequence, take care to select a single session from the list.<br>Once the session is open and the tracing is displayed, touch **PATIENT** again to enter patient information. |

4 When finished, close the Patient window.

# Using Markers

Markers can be used to identify events and areas of interest on a CFM tracing, such as seizure activity, or to record treatments that affect brain activity, such as the administration of anticonvulsant medication. Markers are indicated on a tracing by a dotted green line.

You can place markers while recording or reviewing a tracing, edit markers that are already placed, find markers that are already placed, and view details about placed markers.

## Placing Markers

You have the option of using a predefined (standard) marker or creating a customized, single-use marker. You can place a marker while recording or later while reviewing a session.

### To place a marker:

1 Locate the general area of the tracing where you want to place the marker. If you are reviewing a session, you might need to scroll to the area.

2 Touch **MARKERS**.

3 Touch **STANDARD** to use a predefined marker, or touch **CUSTOM** to create a new, single-use marker. A red marker cursor appears at the right edge of the tracing.

4 Move the red marker cursor to the place of interest by touching the spot in the CFM tracing. Fine-tune the placement by using the marker position scroll buttons to move backward or forward in 15-second increments.

   To place a marker on the next location added during recording, touch to the right of the CFM pen.

5 If you are using a standard marker, touch the desired marker label. If you are adding a custom marker, touch-type an event label (up to 11 characters) and description (up to 40 characters), and then touch **ADD MARKER**.

6 When finished, close the Markers window.

## Editing a Placed Marker

You can change the event label and description for markers that have already been placed on a CFM tracing. The original event name and placement time and location are retained in the marker's permanent history. The marker location cannot be changed or deleted.

You can change the marker information directly from the tracing or from a list.

**Tip:** Since markers cannot be deleted once placed, you can use one of the following procedures to notate any markers that might have been placed in error.

### To change marker information from the tracing:

1 Touch the event label above the CFM tracing.

2 In the Edit Markers window, touch the label or description field and use the displayed keyboard buttons to make the changes, and then touch **ACCEPT**.

3 When finished, close the Edit Markers window.

### To change a marker from a list:

1 Touch **MARKERS**, and then touch **LIST**.

2 Sort the list by touching the column headers, if desired.

3 Touch the label of interest, and then touch **EDIT**.

4 In the Edit Markers window, touch the label or description field, use the displayed keyboard buttons to make the changes, and then touch **ACCEPT**.

5 When finished, close the Edit Markers window.

## Finding Placed Markers

At times you might need to find a marker that is not visible on the screen. Use one of the following methods to find an off-screen marker.

### To find an off-screen marker with scroll buttons:

- Touch the previous or next off-screen marker button under the CFM tracing:

### To find a marker from a list:

1 Touch **MARKERS**, and then touch **LIST**.

2 Sort the list by touching the column headers, if desired.

3 Scroll through the list and touch the marker of interest to move the display to that marker. The marker is highlighted between red lines.

4 Close the Markers window.

### Viewing Marker Details

When you see a marker of interest on a tracing, it might be helpful to see details such as the description, the exact time the marker was placed, the exact position in the tracing, and the original label if it was changed.

**To view marker details:**

- On the CFM tracing, touch the marker label above the tracing.

- Or -

- Touch **MARKERS**, and then touch **LIST**. Select the marker of interest and touch **EDIT**.

## Opening a Session for Viewing

You can open any session that is saved on the hard disk at any time to view it. To restore a session that is archived to a CD, see *Restoring Sessions from CD* on page 27.

NOTE If you wish to protect patient confidentiality, you can suppress the display of patient information while viewing the patient session. See *Changing Patient Information to Display* on page 17 for instructions.

**To open a session from the hard disk:**

1 Touch **PATIENT**, and then touch **OPEN**. If **OPEN** is not available, a patient session is already open. In this case, touch **END** and then **YES** to close the current session, and then touch **PATIENT** again to select the session you want to view.

2 Select the desired session from the list. If the session is long, it might take a few minutes to open.

NOTE To avoid opening multiple sessions in sequence, take care to select a single session from the list.

- Or -

1 Touch **TOOLS**, and then touch **FILES**.

2 Select the desired session from the list, and then touch **DISPLAY**. If the session is long, it might take a few minutes to open.

## Using the CFM 6000 Printer

You can use the internal printer to print the portion of a tracing that is displayed on the screen. You can also specify which combination of graphs — CFM, EEG, impedance — to include in the print.

### Printing a Tracing

When you print a tracing, only the portion displayed on the screen is printed.

### To print a tracing:

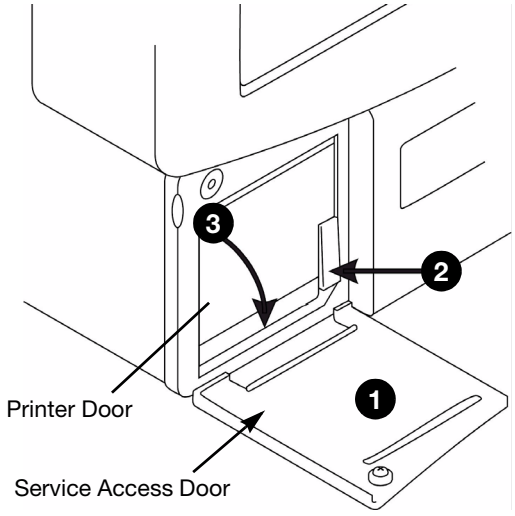
1. Use the positioning buttons until the desired CFM and impedance tracing is displayed.
2. If you want to include a specific area of EEG data, touch **EEG** and use the EEG positioning buttons until the desired data is displayed.
3. Touch the print button at the top left of the screen: . The Print Graphs window displays a print preview.
4. Touch  to enlarge the window, and select the options to include:
   - **PRINT INFORMATION**: Includes patient/file name and ID, patient's date and time of birth, print date and time, CFM software version, and amplifier module serial number.
   - **CFM GRAPH**
   - **EEG GRAPH**
   - **IMPEDANCE GRAPH**
   - **MARKER TEXT**: Includes only the markers and marker text that are displayed on the screen. The marker text prints after the graphs.
5. Select the print size:
   - **MAXIMUM SIZE**: When selected, this option prints graphs in a horizontal row. When this option is not selected, graphs are printed in a vertical stack. You can choose to print graphs vertically only when you select two graphs for printing.
   - **INSIGHT**: When selected, this option prints graphs in gray-scale. When this option is not selected, graphs are printed in the basic (solid) style.
6. Touch **PRINT**. After the data prints, carefully tear off the paper.

## Replacing Printer Paper

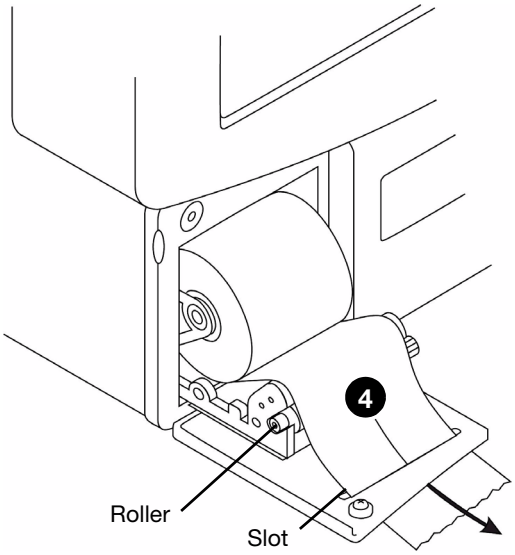
### Required items:

- Thermal paper roll (for reorder information, see *Service* on page 34)

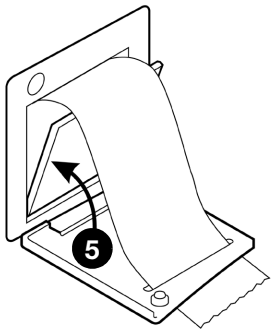
### To replace the printer paper:




1. Open the service access door.
2. Press the bottom of the black switch to open the printer door (3).




4. Place the paper in the printer enclosure. With the paper feeding from the bottom, ensure that it is over the roller and slides down through the slot in the service access door.
5. Close the printer door, and then close the service access door.



# Managing Files

The hard disk in the CFM 6000 can store approximately 20,000 hours of data. If the hard disk is full, an error occurs when you attempt to save another session. In this case, you can archive sessions to CD and delete them from the hard disk to free up disk space. To periodically check the percentage of free space on the hard disk, see *Checking Hard Disk Space* on page 28.

Although your facility can define standards as to when to archive sessions for inclusion in patient records, it is recommended that you archive each session as you complete recording it.

If you want to view sessions that are archived on a CD, you can restore them to the CFM 6000 or use the CFM 6000 Viewer to restore and view them on a Microsoft® Windows® computer.

## Archiving a Session to CD

Archived patient sessions can be:

- Included in the patient's permanent record.
- Stored on the facility network.
- Shared with colleagues for diagnosis and other purposes. You can remove confidential patient identification on archived files.
- Restored and viewed on a Microsoft Windows computer by using the CFM 6000 Viewer.

### Required items:

- Blank standard recordable CDs (CD-R), rated at least 24x speed, 700 MB

**NOTE** Long files might span multiple CD-Rs.

### To archive sessions to CD:

**NOTE** You must stop recording before starting to archive sessions.

1. Touch **TOOLS**, and then touch **FILES**.
2. Scroll through the list and select the sessions to archive. Sort the list by touching the column headers, if desired. If you need to view a session first, select only that session and then touch **DISPLAY**. Sessions that are already archived to CD are indicated by a CD icon ().
3. Touch **ARCHIVE**. The file names, number of sessions, and number of required CDs are listed.
4. If patient sessions are to be shared with colleagues, protect patient confidentiality by touching **SAVE PATIENT NAME AND ID** to clear it.
5. Touch **OK** to open the CD tray.
6. Insert a CD when prompted, and then touch **OK**. If the sessions span multiple CDs, you are prompted for each blank CD.

7 Label each CD when you remove it from the CD tray.

8 After archiving is complete, touch **PRINT** to print the list of archived sessions.

## Restoring Sessions from CD

When you want to view a patient session that is archived on CD, first restore it to the CFM 6000 hard disk.

### To restore a patient session:

1 Touch **TOOLS**, and then touch **RESTORE**.

2 Touch **OPEN TRAY** to open the CD tray, insert the CD, and touch **CLOSE TRAY**.

NOTE Sessions recorded on an prior version of CFM 6000 are indicated by **CFM 1X**. These files are converted to version 2.x when they are restored.

3 Select one or more files to restore. Sort the list by touching the column headings, if desired.

4 Touch **START RESTORE**.

5 Touch **OK** to verify the sessions to be restored. If the archive spans multiple CDs, you are prompted to insert each CD. When the restore is complete, verify that the sessions were restored properly.

## Deleting Files

After you archive sessions to CD, you can delete the files from the hard disk. If you delete a file in error, you can recover it. You must stop recording the current patient session before deleting files.

Permanently removing files from the hard disk to free up space is a 2-step process: deleting the files and then removing them from the trash.

### To delete files from the hard disk:

1 Touch **TOOLS**, and then touch **FILES**.

2 Select the files you want to delete. If you need to view a session first, select only that session and then touch **DISPLAY**.

3 Touch **DELETE**, and then touch **OK** to delete the files.

### To recover files deleted in error:

1 Touch **TOOLS**, and then touch **SYSTEM**.

2 Touch **TRASH**, and select the files you want to recover. If **TRASH** is unavailable, first end the current patient session.

3 Touch **UN-DELETE**, and then touch **OK** to recover the files.

### To permanently remove files from trash:

1 Touch **TOOLS**, touch **SYSTEM**, and then touch **TRASH**. If **TRASH** is unavailable, first end the current patient session.

2 Select the files to be permanently removed, and then touch **DELETE**. Touch **DELETE ALL** to permanently remove all the files from the trash.

### Checking Hard Disk Space

If you do not delete files after you archive patient data or do not permanently remove files from trash, you might need to periodically check the amount of hard disk space used so that you know when you need to free up space.

**To check the amount of free disk space:**

- Touch **TOOLS**, touch **SYSTEM**, and then touch **HARD DISK**. You can see how much disk space is in use, and how much space is used by deleted files in trash.

# Cleaning and Maintenance

**WARNING**

- **To avoid electrical shock hazard, always turn off the power and unplug the device prior to cleaning the device.**
- **To avoid damage to internal electronics and wiring, do not allow liquids to enter the CFM 6000 enclosure or its vents.**

**CAUTION**

- Never autoclave the CFM 6000 or its components as doing so will cause damage and void the warranty.
- Only technically qualified personnel should perform service procedures. On request, Natus Medical Incorporated will provide circuit diagrams, parts lists, and instructions to assist qualified technical personnel to repair the CFM 6000 to the printed circuit board (PCB) level. To obtain service, see *Service* on page 34.
- To prevent bio-contamination, clean exterior of CFM per hospital guidelines.

**NOTICE!**

- Use of sodium hypochlorite (bleach) may damage the instrument surfaces.
- Use only mild cleaning detergents; other cleaning agents may damage the exterior of the CFM 6000 and the CFM cart.
- Dilute cleaning agents according to their label instructions.

## Cleaning the CFM 6000 and the CFM Cart

**Required items:**

- Soft cloth
- Mild cleaning disinfectant (for example, Virex$_{TM}$ Tb, Virustat$_{®}$, Coverage$_{®}$, Sporicidin$_{®}$ cleaners)

**To clean the CFM 6000:**

1. Turn off the power and unplug the power cord before cleaning the outer surfaces of the CFM 6000.
2. Using a soft cloth dampened with mild detergent, wipe the exterior of the CFM 6000, including the touch screen, amplifier module, and power cable.

**To clean the CFM Cart:**

- Using a soft cloth dampened with mild detergent or disinfectant, wipe the CFM cart, including the handle, foot pedal, and both interior and exterior regions of the drawer.

# Tightening the Tilt Adjustment Hinge

If the tilt adjustment of the CFM cart is loose—allowing the CFM 6000 to move backward and forward too easily—the tilt adjustment hinge requires tightening.

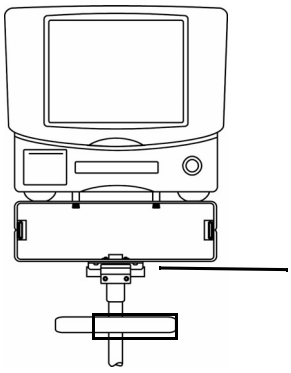
### Required items:

- Allen wrench, small

### To tighten the tilt adjustment hinge:

- Using the Allen wrench, tighten the screws on the tilt adjustment hinge (see Figure 11).

**Figure 11** Tightening the tilt adjustment hinge




# Updating Software

Natus Medical Incorporated periodically updates and releases software for the CFM 6000.

### To identify the software version on your CFM 6000:

- Touch ?, and then touch **ABOUT CFM**.

  The About CFM message box shows the version and build number for the software currently installed on your CFM 6000.

### To update software when version 2.0 or later is already installed:

1. Touch **TOOLS**, touch **SYSTEM**, and then touch **S/W UPDATES**.
2. Touch **OPEN TRAY** to open the CD tray.
3. Place the software disk in the CD tray, touch **CLOSE TRAY**, and then touch **START UPDATE**. The system automatically restarts.
4. After the CFM 6000 restarts, select from the following choices:
   - **INSTALL**. This option removes all system settings and patient sessions, and reformats the hard disk. Use this option when you have archived all patient sessions and want to clean off the hard disk. You need to re-enter all custom settings under **TOOLS**, **SETTINGS** when you use this option.
   - **UPGRADE**. This option retains system settings and patient sessions. However, it is recommended that you archive all patient sessions before upgrading.
   - **FIELD SERVICE**. This option is to be used only when qualified personnel are servicing the device in accordance with the Olympic CFM 6000 Service Manual.

- **CALIBRATE**. This option recalibrates the touch screen.
- **CANCEL**. This option cancels the software update process. You need to restart the CFM 6000 by turning it off and back on.

## Disposing of Product

The CFM 6000 and the CFM cart do not have any components that require special disposal precautions, except as stated for electrodes. Thus, product disposal should be handled according to national laws and regulations.

The fluorescent lamp in the LCD display contains a small amount of Mercury. Follow local ordinances and regulations for disposal.

# Assembling the CFM Cart

### Required items:

- Cart base with foot pedal, screws, and Allen wrenches (5/32 in. and 3/16 in.)
- Cart post with handle and drawer assembly

### To assemble the CFM cart:

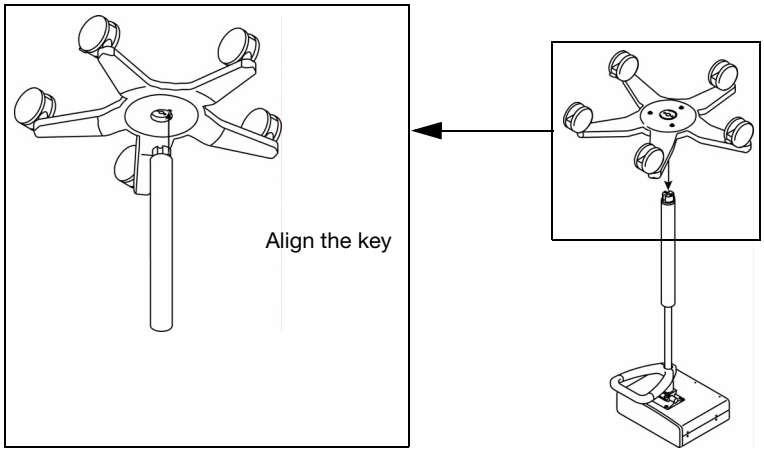
**1** Remove the cart components from the shipping boxes.

**2** Place the cart post upside-down, with the drawer resting on the floor.

NOTE If the post is not at a 90° angle to the drawer, the tilt adjustment may require tightening. Use the small Allen wrench to tighten the screws on the tilt adjustment hinge, which is located on the underside of the drawer.

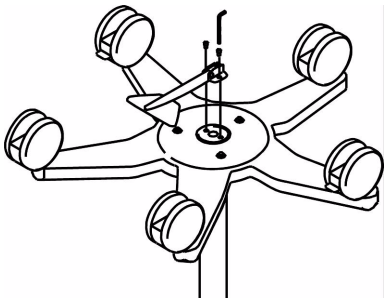
**3** Place the cart base, wheels facing up, onto the post. Align the key on the base with the key slot on the stand (see Figure 12).

**Figure 12** Placing the cart base onto the post




**4** Place the foot pedal on the handle-side of the base. Ensure that the foot pedal label is facing the drawer, and then use the larger Allen wrench to securely tighten the two screws (see Figure 13).

**Figure 13** Securing the foot pedal



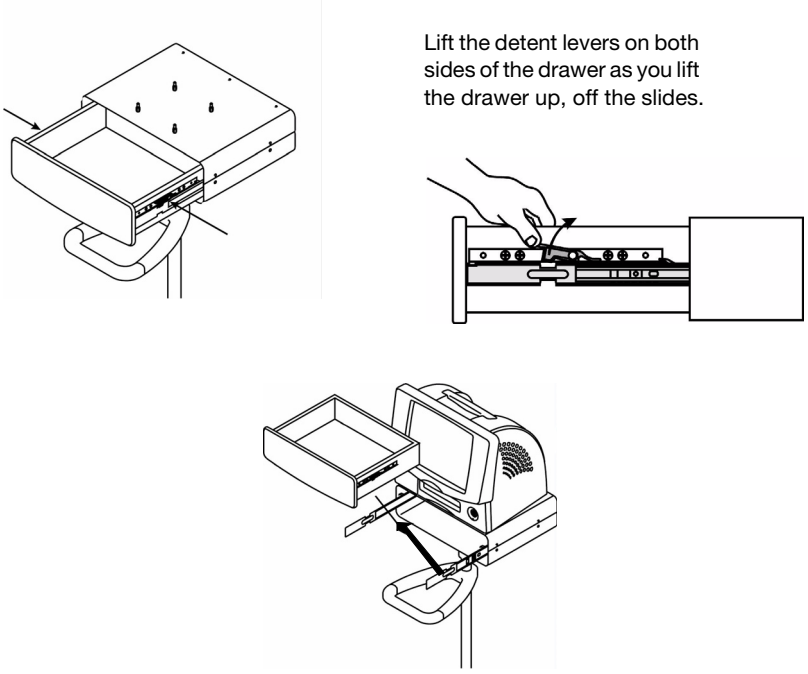
**5** Carefully turn the stand over, leveraging the handle and the base.

### To place the CFM 6000 on its cart:

**1** Remove the drawer from the CFM cart:

- **a** Open the drawer.
- **b** Lift the detent levers on both sides of the drawer slides as you lift the drawer up and off the slides (see Figure 14).

**Figure 14** Removing the drawer

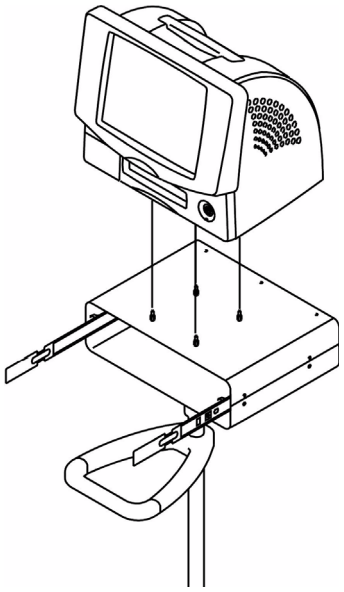



**2** Remove the tape securing the thumbscrews, and ensure that the thumbscrew spacers are not resting on the threads. The spacers should spin freely.

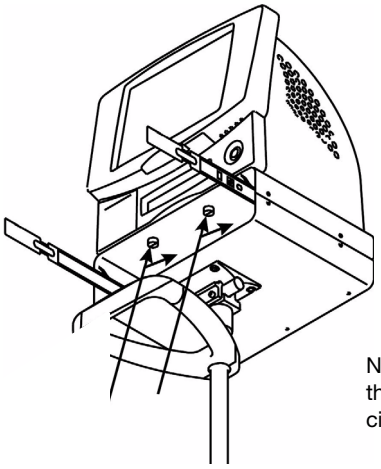
**NOTE** If the thumbscrew spacers rest on the threads, they act as a jam nut, preventing secure placement of the CFM 6000 on the cart.

**3** Place the CFM 6000 on the top of the drawer enclosure, visually aligning the device to the thumbscrews (see Figure 15). The thumbscrew heads are located inside the drawer cavity. To maintain balance, tighten the thumbscrews incrementally in a circular or X-pattern.

**Figure 15** Placing the CFM 6000 on its cart



First, place the CFM 6000 on the top of the drawer enclosure, visually aligning the device to the thumbscrews.

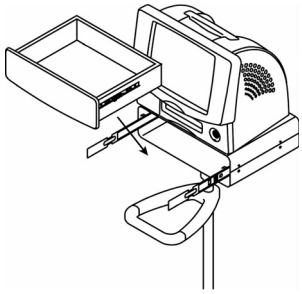


Next, incrementally tighten the thumbscrews in a circular or X-pattern.

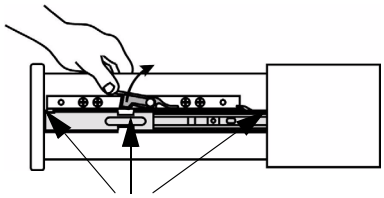
**4** Place the drawer into its cavity on the CFM cart (see Figure 16):

- **a** Fully extend the slides.
- **b** Place the drawer down onto the slides.
- **c** Slide the drawer into position. An audible click indicates that the drawer is locked into position. Confirm that the detent lever secures the drawer on both slides (see Figure 16).

**Figure 16** Installing the drawer



With the slides fully extended, place the drawer down onto the slides.

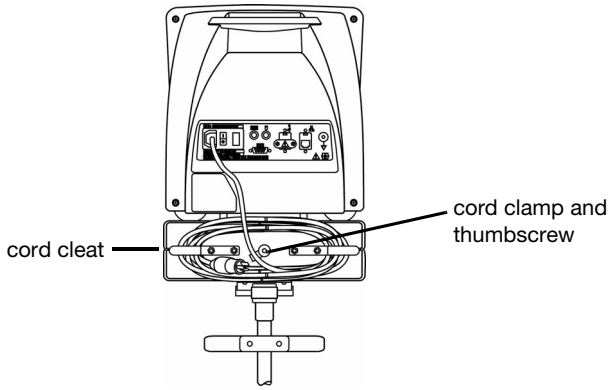


Each slide locks in position in three locations and an audible click sounds.

**5** Secure the CFM's power cord to the CFM cart:

- **a** Plug the power cord into the power receptacle on the back of the CFM 6000.
- **b** Unscrew the thumbscrew on the back of the drawer on the CFM cart (see Figure 17). Select a cord clamp—small diameter for a European power cord, or larger diameter for a North American power cord.
- **c** Place the appropriate cord clamp on your power cord, and then tighten the thumbscrew.
- **d** Wrap any excess power cord around the cord cleats on the back of the drawer (see Figure 17).

**Figure 17** Securing the power cord to the CFM Cart




### To check the function of the CFM cart:

1. Confirm that the height of the cart can be adjusted. While stepping on the foot pedal, pull the handle up, and then push it down to ensure that the pole raises and lowers (see Figure 2 on page 7).
2. Ensure that the tilt adjustment is firm. Place one hand on top of the CFM 6000 and the other on the bottom of the drawer, and then firmly tilt the drawer forward and backward (see Figure 2 on page 7).
3. Ensure that the drawer opens and closes with ease, and that it latches when in the closed position.
4. Confirm that the two locking caster wheels lock and unlock (see Figure 1 on page 7).

# Troubleshooting

If you have problems when operating the CFM 6000, look in the following table for a solution. If you cannot find a solution in this table, contact Olympic Medical.

| Problem | Possible Cause | Solution |
|---|---|---|
| Screen frozen — doesn't respond | System error | ■ Turn the power off, and then on.<br>■ If the problem persists, obtain technical support from your Natus Medical Incorporated representative. |
| Screen is black | No power | Ensure that the power cord is plugged in and the power is turned on. |
| | Blown fuse | Replace the fuse. |
| Paper jam | Paper misfeed | ■ Ensure that the paper is fed through the slot in the service access door.<br>■ Load the paper according to the instructions in *Replacing Printer Paper* on page 25. |

| Problem | Possible Cause | Solution |
|---|---|---|
| Cannot open file | Not a CFM file | ■ The CFM 6000 can only display files that are in CFM format.<br>■ If a file was compressed using desktop software, such as WinZip® or Stuffit®, decompress the file before restoring it to the CFM 6000. |
| | File is corrupt | Contact Technical Support. |
| Patient name and ID missing from restored file | Name and ID were removed during archive | For confidentiality, patient data was removed when the patient file was archived to CD-R. |
| High impedance | Electrodes not seated | Ensure that the electrodes are firmly adhered to the patient's head. |

# Service

Do not use malfunctioning equipment. Biomedical technicians may perform in-field service; refer to the *Olympic CFM 6000 Service Manual* for troubleshooting, repair procedures, and parts ordering information.

### To return the CFM 6000 for service:

1. Contact Natus Medical Incorporated or your local CFM 6000 distributor for return merchandise authorization (RMA) and a shipping container.
2. Clean the device, and securely package it in the original shipping container, if possible, and include:
   a. The completed RMA form.
   b. A purchase order (PO) number to cover the repair of any device not under warranty.
3. Ship the equipment prepaid to Natus Medical Incorporated or your local distributor.

# Replacement Parts

NOTE
- Use only Natus Medical–approved parts with the CFM 6000.
- For a complete list of available parts and accessories, contact Olympic Medical or your Olympic CFM 6000 distributor.

## Contact Information

To order parts and accessories or to obtain service, contact:

### In the United States and Canada

Natus Medical Incorporated

| | |
|---|---|
| Toll-free: | 1-800-308-8684 (U.S. and Canada) |
| Phone: | +1-650-802-0400 (international) |
| Customer Service Fax: | +1-650-802-6620 |
| Technical Service Fax: | +1-650-802-8680 |

### In Asia and the European Union

Contact your Olympic CFM 6000 distributor.

## CFM 6000 Catalog Items

When ordering, provide the item number to the customer service representative.

**Table 3** Accessories

| Item Description | Catalog Number |
|---|---|
| Amplifier module clips, bag of 5 | 62065 |
| Olympic CFM cart | 62080 |
| Electrode cream, 3.5-oz. tube | 60119 |
| Electrodes, disk (available only in the United States) | 60126 |
| Electrodes, low-impedance (needle type): box of 10 | 62056 |
| Electrodes, low-impedance (needle type): box of 50 | 62057 |
| Electrodes, hydrogel: bag of 20 | 62050 |
| Electrodes, hydrogel: box of 100 | 62051 |
| NuPrep™ Skin Prep Paste, 4-oz. tube | 62060 |
| Paper: thermal, 50-mm wide roll | 62066 |
| Publication: *An Atlas of Amplitude-Integrated EEGs in the Newborn* | 62070 |
| Publication: *Atlas of Neonatal Electroencephalography* | 62071 |

# Standards and Compliance

### Electrical Safety Standards and Classification

- European Union Notice (EN) 60601-1-1 / International Electrotechnical Commission (IEC) 60601-1, Amendments I and II
- Canadian Standards Association (CSA) C22.2 No. 60601-1-M90
- Underwriters Laboratory (UL) 2601-1

### EMI/EMC

- IEC 60601-1-2

### Regulatory Classification

- Food and Drug Administration (FDA), Class II
- Health Canada, Therapeutic Products Directorate, Class III
- European Union (EU) Medical Device Directive (MDD), Class IIb

# Specifications

## Intended Use

The Olympic CFM 6000 is intended to monitor the state of the brain by acquisition of EEG signals in the intensive care unit, operating room, and for clinical research.

## Dimensions

### CFM 6000 Size

13.70-in. wide × 12.25-in. high × 11.25-in. deep
34.8-cm wide × 31.1-cm high × 28.6-cm deep

### CFM 6000 Weight

17.5 lb 7.9 kg

### CFM cart Size

38.75–49.75-in. high* × 25-in. diameter footprint
98.42–126.36-cm. high* × 63.5-cm. diameter footprint

*Adjustable, measurement to top of drawer.

### CFM cart Weight

40 lb 18.1 kg

## Computer and Connections

### Display

- SVGA video
- Liquid-crystal display (LCD) touch screen
- 800 × 600 pixel resolution; 32-bit colors
- Minimum viewing angle of 120 degrees

### Processor

- P5-266–MHz processor or equivalent
- 256-MB RAM

### Internal Components

- CD-RW drive; internal thermal printer
- 80-GB hard drive capacity (minimum)

### External Connections

- RS-232 I/O port
- RJ-45 (10/100) Ethernet port
- USB port for 60601-1–approved devices (see the USB port precautions on page 3)
- PS2 standard keyboard serial port
- PS2 standard mouse serial port
- Hospital-grade power cord

### Connecting Cables

Cables that connect to the I/O ports must be of the following types and no greater than the following lengths:

- USB: two meters, shielded
- Serial: four meters, shielded
- Ethernet: five meters, Category 5

**Note:** Mouse and keyboard ports are for service use only.

## Printer Paper

- Thermal paper roll, 50-mm wide
- Five-year shelf life if stored at less than 77ºF (25ºC), 65% relative humidity
- Image life approximately five years if stored at less than 77ºF (25ºC), 45–65% relative humidity

## CFM cart Features

- Drawer tilts 15° forward and 15° backward
- Five-legged base with swivel casters; two locking casters
- Convenient handle for pushing, pulling, and swivelling
- Easy height adjustment with foot-actuated pedal
- Storage drawer for keeping brain monitoring supplies nearby and ready for use

## Power Requirements

- Voltage: 100–240 V~, universal input, single phase
- Consumption: 1.0A
- Frequency (current): 47–63 Hz

### Ground

Does not exceed 0.2Ω (CFM 6000 and cord)

### Fuses

Two (2) internal 3AG, 2.5A, Slo-Blo, 250 V~ with external access

## Environment

### Temperature

- Operating: 65–85°F 18–29°C
- Shipping: -13–158°F -25–70°C
- Storage: -13–113°F -25–45°C

### Relative Humidity (RH)

- Operating: 0–95%, non-condensing
- Non-operating: 0–100%, condensing

### Operating Altitude

Up to 6,560 ft. 2,000 m

### Operating and Non-Operating Pressure

500–1060 hPa 14.7–31.3 inHg

## 60601 Classification Notes

- Type of protection against electrical shock: Class I equipment
- Type BF patient-applied parts
- Ordinary equipment (IXP0)
- Not suitable for use in the presence of flammable anesthetics
- Continuous operation